

REMARKS

In the Office Action mailed October 4, 2004, claims 1 and 2 were rejected under 35 USC § 102(b) as being anticipated by Wallace (U.S. Patent No. 2,667,875).

Claims 3-5 were allowed in the Office Action of October 4, 2004.

Applicants have amended claim 1 in order to correct for a typographical error in Applicants' previously submitted Amendment of August 10, 2004 that mistakenly used the word "proximately" instead of the word "proximally." Applicants are not relying on this correction of claim 1, to define over the current reference of Wallace applied against claim 1, but are simply correcting a typographical error.

Applicants respectfully traverse the § 102(b) rejection to claim 1 in view of Wallace. Respectfully, Wallace does not disclose a tubular balloon with distal and proximal ends that are attached to a shaft a distance apart that is less than an unattached length of the balloon therebetween whereby a plurality of gathers is formed.

Wallace discloses an inflatable retention catheter 10 with an elongated, flexible tubular member 12 (see column 3, lines 13-15 of Wallace). A flexible bag 26 made of a pair of flexible, non-elastic annular members 28 is attached to the tubular member 12 (see Wallace at column 3, lines 32-34). An inner marginal portion 30 of each member 28 is flange-like and is hermetically sealed to the tubular member 12 in spaced relation to the corresponding portion of the other annular member 28 (see Wallace at column 3, lines 34-38).

Fig. 2 is a cross-sectional view of the catheter 10 shown in Fig. 1 (see Wallace at column 3, lines 3-5). Fig. 1 shows the bag 26 in a manually collapsed and deflated state (see Wallace at column 3, lines 51-54). Therefore, Fig. 2 also shows the bag 26 in a manually collapsed and deflated state. The inner marginal portion 30 of each annular member 28 is

positioned on the tubular member 12 a distance that is equal to the unattached length of the bag 26 formed by the pair of annular members 28. As shown in the deflated state in Figs. 1 and 2, there are no gatherers formed in the bag 26.

Page 2 of the Office Action mailed October 4, 2004 states that the bag 26 in Wallace or in any balloon inherently has gathers and folds. Applicants do not dispute the fact that the bag 26 of Wallace could be manipulated in order to form one or more gathers or folds thereon. The plurality of gathers in claim 1 of Applicants' application, however, are formed by attaching the distal and proximal ends of the balloon a distance apart that is less than an unattached length of the balloon. This particular element of claim 1 of Applicants' application is not disclosed or rendered obvious by the catheter 10 in Wallace. The fact that Wallace may disclose gathers or folds is not enough to render claim 1 of Applicants' application obvious because Wallace does not disclose or render obvious the particular way the gathers are formed as set forth in claim 1 of Applicants' application.

By way of example, Applicants' application describes one way of attaching the distal and proximal ends of the balloon a distance apart that is less than an unattached length of the balloon. Cuff 252 may be attached to shaft 214 in a conventional manner but located thereon so that the other cuff 256 extends naturally approximately 1 mm beyond the tip 240 (see page 10, lines 18-22 of Applicants' application). The balloon 218 is then bunched up or gathered over the shaft 214 until cuff 256 is positioned slightly proximal to tip 240 (see Applicants' application at page 10, line 22 to page 11, line 1). Cuff 256 is then glued to shaft 214 at a corresponding position (see Applicants' application at page 11, lines 1-2). Figs. 9 and 10 of Applicants' application show one exemplary embodiment of this type of arrangement.

Referring now to Wallace, the inner marginal portions 30 of the annular members 28 are in spaced relation to the corresponding portion of the other annular member 28 (see Wallace

at column 3, lines 34-38). The inner marginal portions 30 are not attached to the tubular member 12 a distance apart that is less than the unattached length of the annular members 28. The inner marginal portions 30 are located on the tubular member 12 in positions that correspond naturally to those of each annular member 28 as demonstrated in Figs. 1 and 2 of Wallace in which the bag 26 is in the deflated state and no gathers or folds are formed. Additionally, the inner marginal portions 30 are positioned so each annular member 28 is symmetric with the other hence further demonstrating that the inner marginal portions 30 are located in a natural position and are not spaced apart a distance that is less than the unattached length of the annular members 28 so as to form a plurality of gathers.

Further, it would not have been obvious for one having ordinary skill in the art to modify Wallace so that the inner marginal portions 30 were attached to the tubular member 12 a distance apart that is less than an unattached length of the annular member 28. The fact that a reference can be modified does not render Applicants' claim 1 obvious unless the reference also suggests the desirability of the modification. Nowhere in Wallace is it mentioned that it would be desirable to rearrange the bag 26 in a manner as set forth in claim 1 of Applicants' application.

Further, the Office Action of October 4, 2004 states that gathers and folds will be formed when the bag 26 is inserted into the urethra (see page 2 of the Office Action of October 4, 2004). Therefore, if one's goal was to form gathers or folds in the bag 26, Wallace allegedly teaches that this can be accomplished through insertion into the urethra. Therefore, one would not be motivated to form a plurality of gathers by configuring a balloon in the method set forth in claim 1 of Applicants' application because Wallace already teaches a preferred manner of producing the gathers or folds.

Additionally, modification of Wallace so that the inner marginal portions 30 were moved closer to one another, could interfere with the flow of air through duct 34 into the bag 26. As shown in the Figures of Wallace, the inner marginal portions 30 are already positioned relatively close to one another and making their positioning closer could block the duct 34 and as such it would not have been obvious for one having ordinary skill in the art to make such a modification of Wallace because doing so could potentially create problems in ensuring that air is delivered to the bag 26 in order to inflate the bag 26.

Applicants respectively submit that claim 1 defines over Wallace and is in condition for allowance. Further, Applicants also submit that claim 2 that depends from claim 1 is in condition for allowance as the rejection to claim 2 is made moot due to the allowance of claim 1.

Applicants respectfully submit that all claims are allowable and that the application is in condition for allowance. Favorable action thereon is respectfully requested. The Examiner is encouraged to contact the undersigned at her convenience to resolve any remaining issues or should the Examiner have any further questions.

Respectfully submitted,

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